

## EU Declaration of Conformity

for a medical device class I (according to the EU regulation 2017/745, annex IV)

The manufacturer:

**Franz Mensch GmbH**  
Werner-von-Siemens-Str. 2  
D - 86807 Buchloe

declares under sole responsibility, that the class I medical device according to the classification rules of the EU regulation 2017/745, annex VIII

Item REF	27003
Description	Nitrile gloves Safe Long   powder-free
Brand	Hygostar
Version	Packing unit: Carton Color: White Size: 10/XL Length: 30cm

complies and meets all the provisions of the conformity assessment procedure of the EU regulation 2017/745 (annex I).

in accordance with confirmed records, test results or certificates, complies/comply with the requirements of the relevant harmonization legislation:

EN 455-1:2020  
EN 455-2:2015+A1:2011  
EN 455-3:2015  
EN 455-4:2009

The achieved performance levels of this medical device correspond to:

Signed for and on behalf of Franz Mensch GmbH,

Buchloe, 31.05.2021



Amanda Kreuzmann  
Head of Quality Management